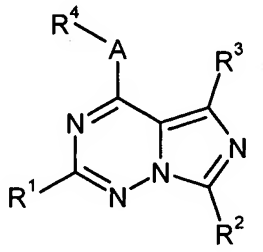
AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Currently amended) A compound of the formula



(I),

in which

R^1 denotes 5- to 10-membered heteroaryl, which can be substituted by up to 3 substituents selected independently of one another from the group consisting of oxo, halogen, carbamoyl, cyano, hydroxyl, (C_1-C_6-alkyl)carbonyl, trifluoromethyl, trifluoromethoxy, nitro, C_1-C_6-alkyl, C_1-C_6-alkoxy and -NR^5R^6,

where

R^5 and R^6 independently of one another denote for C_1-C_6-alkyl or

R^5 and R^6, together with the nitrogen atom to which they are bonded, denote a 5 to 8-membered heterocycle, which is optionally substituted by C_1-C_6-alkyl or C_1-C_6-hydroxyalkyl,

R^2 denotes C_1-C_6-alkyl or C_3-C_4-cycloalkyl,

R^3 denotes methyl,

A denotes oxygen or NH,

and

R^4 denotes C_6–C_{10}-aryl, which can be substituted by up to 3 substituents selected independently of one another from the group consisting of halogen, formyl, carboxyl, carbamoyl, cyano, hydroxyl, trifluoro-methyl, trifluoromethoxy, nitro, C_1-C_6-alkyl, C_1-C_6-alkoxy, 1,3-dioxa-propane-1,3-diyl, C_1-C_6-alkylthio and $-NR^7R^8$,

in which

R^7 and R^8 independently of one another denote hydrogen, C_1-C_6-alkyl or C_1-C_6-alkylcarbonyl,

~~and their salts, solvates and/or solvates of the salts~~ or a salt thereof.

2. (Currently amended) A compound as claimed in claim 1, where

R^1 denotes 5- to 10-membered heteroaryl, which can be substituted by up to 3 substituents selected independently of one another from the group consisting of oxo, C_1-C_6-alkyl, C_1-C_6-alkoxy and $-NR^5R^6$,

where

R^5 and R^6 independently of one another denote C_1-C_6-alkyl or

R^5 and R^6, together with the nitrogen atom to which they are bonded, form a 5 to 8-membered heterocycle, which is optionally substituted by C_1-C_6-alkyl or C_1-C_6-hydroxyalkyl,

R^2 denotes C_1-C_6-alkyl,

R^3 denotes methyl,

A denotes oxygen or NH,

and

R^4 denotes phenyl, which can be substituted by up to 3 substituents selected independently of one another from the group consisting of halogen, C_1-C_6-alkyl and C_1-C_6-alkoxy,

~~and their salts, solvates and/or solvates of the salts~~ or a salt thereof.

3. (Currently amended) A compound as claimed in claim 1 **[[**and**]]** or claim 2, where

R^1 denotes thienyl, furyl, thiazolyl or pyridyl, which in each case can be substituted by up to 2 substituents selected independently of one another from the group consisting of oxo, C_1-C_6-alkyl, C_1-C_6-alkoxy and $-NR^5R^6$,

where

R^5 and R^6 independently of one another denote C_1-C_6-alkyl or

R^5 and R^6, together with the nitrogen atom to which they are bonded, form a 5 to 8-membered heterocycle, which is optionally substituted by C_1-C_6-alkyl or C_1-C_6-hydroxyalkyl,

R^2 denotes C_1-C_6-alkyl,

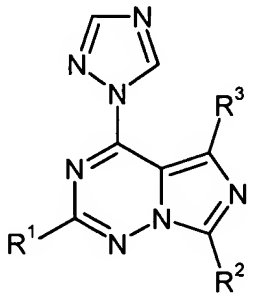
R^3 denotes methyl,

A denotes oxygen or NH,

R^4 denotes phenyl, which is substituted by up to 3 C_1-C_6-alkoxy radicals,

~~and their salts, solvates and/or solvates of the salts~~ or a salt thereof.

4. (Currently amended) A process for the preparation of ~~compounds~~ a compound as claimed in claim 1, characterized in that ~~compounds~~ a compound of the general formula

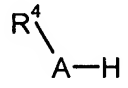


(II),

in which

R^1, R^2 and R^3 have the meanings indicated in claim 1,

[[are**]]** is reacted with ~~compounds~~ a compound of the formula



(III),

in which

R^4 and A have the meanings indicated in claim 1,

to give ~~compounds~~ a compound of the formula (I) ~~and these are~~ which may be optionally reacted with **[[**the**]]** an appropriate ~~(i) solvents and/or (ii) bases or acids~~ base or acid to give ~~their solvates, salts and/or solvates of the salts~~ a salt thereof.

5. Canceled

6. (Currently amended) A medicament containing ~~at least one of the~~ one or more compounds as claimed in claim 1 and at least one pharmaceutically tolerable, essentially nontoxic vehicle or excipient.

7. (Currently amended) A method for the treatment ~~and/or prophylaxis~~ of ~~neurodegenerative disorders~~ a neurodegenerative disorder comprising administering to a human or animal an effective amount of a compound of claim 1 or a medicament of claim 6.

8. (Currently amended) A method for the treatment ~~and/or prophylaxis~~ of cancer, ~~neurodegenerative disorders~~ or ~~psychiatric disorders~~ a psychiatric disorder comprising administering to a human or animal an effective amount of a compound of claim 1 or a medicament of claim 6.

9. (Previously presented) The method as claimed in claim 7, wherein the neurodegenerative disorder is Parkinson's disease.

10. (Previously presented) The method as claimed in claim 8, wherein the psychiatric disorder is schizophrenia.

Claims 11-13. Canceled.

REMARKS

Claims 1-4 and 6-10 are pending in the subject application. Claims 1-4 and 6-8 are amended herein to more clearly define the claimed subject matter. No new matter has been added by the amendments. Support for the amendments is found throughout the application and claims as originally filed. Claims 11-13 have been canceled without prejudice. Applicants respectfully reserve the right to pursue any non-elected, canceled or otherwise unclaimed subject matter in one or more continuation, continuation-in-part, or divisional applications.

It is submitted that the claims, herewith and as originally presented were in full compliance with the requirements of 35 U.S.C. § 112. The amendment of the claims, as presented herein, is not made for purposes of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112. Rather, this amendment is made simply for clarification and to round out the scope of protection to which Applicants are entitled. Furthermore, it is explicitly stated that the herewith amendment should not give rise to any estoppel.

Reconsideration and withdrawal of the objections to and the rejections of this application in view of the amendments and remarks herewith, is respectfully requested, as the application is in condition for allowance.

Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 1-4 and 6-13 stand rejected as being indefinite as allegedly unclear as to whether the claims are compound claims or composition claims because of the recitation of the terms "and their salts, solvates and/or solvates or their salts" and "compounds" in claims 1-4. Further, claim 6 stands rejected because the term "at least one of compounds as claimed in claim 1" is allegedly unclear.

Without conceding the validity of the Examiner's rejections, claims 1-3 have been amended to recite "or a salt thereof" instead of "and their salts, solvates and/or solvates of the salts". Applicants feel that this amendment sufficiently clarifies that claims 1-3 refer to compound claims and not composition claims. Similarly, claim 4 has been amended to recite a process of preparing a compound or salt thereof as opposed to "compounds". Finally, claim 6 has been amended to recite "one or more

compounds of claim 1" as suggested by the Examiner. Support for these amendments can be found throughout the application and claims as originally filed. Applicants respectfully request reconsideration and withdrawal of these rejections.

Claims 11-13 stand rejected because the term "a process for the control of cancer" is allegedly unclear. Without conceding the validity of the Examiner's rejection and solely to expedite the prosecution of the present application, Applicants have canceled claims 11-13. The rejection is therefore moot. Applicants respectfully request reconsideration and withdrawal of these rejections.

Rejections under 35 U.S.C. § 112, First Paragraph

Claims 1-4 and 6 stand rejected as failing to provide enablement for the making of a solvate of a compound of the invention. Without conceding the validity of the Examiner's rejection and solely to expedite the prosecution of the present application, claims 1-4 have been amended to recite "or a salt thereof." Applicants respectfully request reconsideration and withdrawal of the rejection.

Claims 7, 8 and 11-13 stand rejected as failing to reasonably enable the treatment or prevention of neurodegenerative diseases, psychiatric disorders, or cancer in general. As stated above, claims 11-13 have been canceled without prejudice. With respect to claims 7 and 8, Applicants respectfully disagree and traverse.

As an initial matter, the Examiner alleges that claims 7 and 8 are "reach through claims...drawn to a mechanistic, receptor binding or enzymatic functionality in general format." Applicants respectfully disagree. Claims 7 and 8 are drawn to methods of treating or preventing cancer, neurodegenerative disorders or psychiatric disorders with a compound or composition of the present invention. While the particular activity of the compounds, namely inhibition of PDE10A may be relevant to the treatment or prophylaxis claimed, the claim is directed to administering a specific compound or composition. The claim does not encompass the treatment of said diseases using *any* compound that inhibits PDE-10A but only those described in the present application. Thus, the claims are not reach through claims and should not be treated as such.

Furthermore, although Applicants strongly disagree with the Examiner's allegation that the specification is viewed as lacking enablement for prevention of any of the diseases recited, the pending claims have been amended to delete the terms of "and/or prophylaxis," solely to expedite the prosecution of the present application, and without prejudice to Applicants' right to pursue them in one or more continuation, divisional or continuation-in-part applications. In view of these amendments and the following discussions, Applicants respectfully submit that the rejection must be withdrawn.

With regard to the methods of treatment of the present claims, the test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. *U.S. v. Telectronics, Inc.,* 857 F.2d 778, 785 (Fed. Cir. 1988). The examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. *Manual of Patent Examining Procedure* ("MPEP") § 2164.04 (citing *In re Wright,* 999 F.2d 1557, 1562 (Fed. Cir. 1993)).

Accordingly:

> A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented *must be taken as being in compliance with the enablement requirement* ... unless there is a *reason to doubt the objective truth of the statements* contained therein which must be relied on for enabling support
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> * * *
>
> It is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement.

Id. (emphases added).

Applicants respectfully submit that whether or not the scope of a claim is broad is irrelevant to the assessment of the enablement of the claim. The question is whether those skilled in the art would have been able to make and use the claimed invention based on the disclosure. *(See U.S. v. Telectronics, Inc.,* at 785).

Applicants respectfully submit that the pending claims are enabled because the specification "contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented." *Id.*

For example, the specification teaches that the compounds of the invention are PDE 10A inhibitors and that "PDE 10A hydrolyzes both cAMP and cGMP" (Page 1, line 16). Similarly, the specification teaches that the compounds of the present invention are useful in "treatment of further diseases which can be treated by influencing the cGMP level and/or the cAMP level, such as dementia, stroke, craniocerebral trauma, Alzheimer's disease, dementia with frontal lobe degeneration, Lewy body dementia, vascular dementia, attention deficit syndrome, attention and concentration disorders, affective disorders, psychoses, neuroses, mania or manic depressive disorders, Pick's disease, pain and epilepsy" (Page 27, lines 1-7). The specification further describes "Idiopathic Parkinson's disease", "tumors", "psychoses", "schizophrenia and related schizoaffective disorders", and "neuropsychiatric changes" (Page 26). Similarly, it is disclosed that the claimed compounds can be prepared by synthetic procedures described in Schemes 1 and 2 and in Examples 1-27. Therefore, it is clear that a sufficient guidance is provided in the specification so as to allow those of ordinary skill in the art to make and use the claimed invention, as required by 35 U.S.C. § 112, first paragraph.

Nonetheless, the Examiner further alleges that there is insufficient "evidence that the instantly disclosed tests are highly predictive for all the uses disclosed and embraced by the claim language for the intended host," and thus that one skilled in the art would have to undergo an undue amount of experimentation in consideration of factors 1-6 set forth in *In re Wands.* Applicants respectfully disagree with the allegations.

To the extent that the IC_{50} data provided herein are *in vitro,* Applicants point out that to demonstrate utility, Applicants need only show that any given compound is pharmacologically active *in vitro. See Cross v. Iizuka,* 753 F.2d 1040, 1051 (Fed. Cir. 1985) ("Successful *in vitro* testing will marshal resources and direct the expenditure of effort to further *in vivo* testing of the most potent compounds, thereby providing an immediate benefit to the public, analogous to the benefit provided by the showing of an *in vivo* utility.) (citations omitted). Further, "[i]f a statement of utility in the specification contains ... a connotation of how to use, and/or the art recognizes that standard modes of administration are known and contemplated," the enablement requirement is satisfied. *Manual of Patent Examination and Procedure* § 2164.01(c) (citing, *inter alia, In re Brana, 51* F.3d 1560, 1566 (Fed. Cir. 1993)).

Moreover, "[a]n *in vitro* or *in vivo* animal model in the specification, in effect, constitutes a 'working example' if the example 'correlates' with a disclosed or claimed method" (MPEP § 2164.02). Explaining further, MPEP § 2164.02 states:

> "[I]f the state of the art is such that a particular model is recognized as correlating to a specific condition, then it should be accepted as correlating unless the examiner has evidence that the model does not correlate. Even with such evidence, the examiner must weigh the evidence for and against correlation and decide whether one skilled in the art would accept the model as reasonably correlating to the condition."

Finally, MPEP § 2164.02 also recognizes that "a rigorous correlation is not necessary where the disclosure of pharmacological activity is reasonable based upon the probative evidence" (quoting *Cross v. Iizuka,* 753 F.2d 1040, 1050, 224 USPQ 739, 747 (Fed. Cir. 1985)).

In view of the foregoing, it is clear that sufficient guidance is provided in the specification so as to allow those of ordinary skill in the art to make and use the claimed invention. Indeed, the claimed invention is directed to the use of obtainable compounds. The skilled artisan can readily determine the IC_{50} for any of the compounds encompassed by the claims by using the methods described in the specification, which can

be readily used to determine that a synthesized compound is useful in the treatment of the diseases recited in the claims. Moreover, the determination by a physician as to whether a claimed compound is effective in treating a recited disease in a given patient is a type of determination that is always made by physicians for every pharmaceutical. Indeed, the determination is a routine one that every physician is prepared to make, and which requires little or no effort. Therefore, Applicants respectfully submit that one reasonably skilled in the art could make or use the invention as claimed without undue experimentation.

In sum, Applicants respectfully submit that: (1) the specification provides sufficient information and guidance to those of ordinary skill in the art to make and use the claimed invention; (2) the Examiner did not provide any factual or legal basis to doubt that the claims are enabled; and (3) to the extent any experimentation is necessary, such experimentation is not undue. Therefore, Applicants respectfully request that the rejection of the claims under 35 U.S.C. § 112, first paragraph be reconsidered and withdrawn